

### **REMARKS**

The non-final Office Action mailed March 18, 2008 has been reviewed and the comments therein were carefully considered. Claims 1-11 and 27-38 have been withdrawn from consideration as being drawn to non-elected inventions. Independent claims 12 and 21 have been amended to clarify the invention. Claims 12-26 and 39-48 are currently pending.

#### **Claim Rejections Under 35 USC §103**

Claims 12-15, 17-26, 39-41, and 44-46 were rejected under 35 USC §103(a) as being unpatentable over Lebel, et al., U.S. Publication No. 2002/0016568 A1 ("Lebel"), in view of Mayer, U.S. Publication No. 2002/0010597 ("Mayer"). The Applicants respectfully disagree and traverse the rejection.

Independent claim 12 has been amended to clarify the invention, and now states the following:

12. An implantable drug delivery device for delivering at least one drug to a patient comprising in combination:

(a) at least one reservoir each containing at least one drug;  
(b) a drug scheduling module for determining whether the drug should be replenished;

(c) an appointment scheduling module automatically initiated by the drug scheduling module and without scheduling input contemporaneously provided by the patient, for automatically scheduling an appointment to replenish the drug in the device; and

(d) a telemetry module providing bi-directional communications with an external device for allowing the appointment scheduling module to schedule the appointment,

wherein the drug scheduling module receives data about the implantable drug delivery device, wherein the data is selected from the group consisting of drug usage information and drug management data.

The amendment is supported at least by paragraphs 52 and 58-59 and Figure 10 of the application as originally filed. Neither Lebel nor Mayer discloses a drug scheduling module that receives data about an implantable drug delivery device wherein the data is selected from the group consisting of drug usage information and drug management data, determines whether the

drug should be replenished and automatically initiates an appointment scheduling module without scheduling input contemporaneously provided by the patient, for automatically scheduling an appointment to replenish the drug in the device. Lebel is directed to an implantable medical device and an external communication device that gives an alarm to a patient when the medication remaining in the implantable medical device becomes less than a predefined low-reservoir threshold. However, as recognized by the Examiner, Lebel does not disclose an appointment scheduling module initiated by a drug scheduling module. Further, the external communication device of Lebel is not an appointment scheduling module that is within the implantable drug delivery device as claimed in claim 12 of the present application.

Mayer does not remedy the deficiencies of Lebel. Mayer is directed to a set of software tools for a consumer to use for taking control of his or her own medical care. (See Abstract of Mayer). An appointment making tool is disclosed in paragraph 50 of Mayer: "This tool confirms, tracks and keeps appointments organized. For example, a patient needing an appointment for a physical." Thus, Mayer teaches appointment scheduling upon receiving a request from a *patient* for an appointment, as opposed to having a separate entity (i.e., a drug scheduling module) automatically initiating the request for an appointment. The Office Action ignores that there is no teaching in Mayer of "an appointment scheduling module automatically initiated by the drug scheduling module, and without scheduling input contemporaneously provided by the patient, for automatically scheduling an appointment to replenish the drug in the device," as claimed in amended independent claim 12.

Although a pharmacist tool is disclosed in paragraph 39 of Mayer to give "an estimation of compliance and can prompt for refills to improve compliance," there is no further disclosure with respect to prompting for refills, such as how the pharmacist tool could actually provide a prompt.

There is no teaching in Mayer that the pharmacist tool (paragraph 39) communicates in any way with the appointment making tool (paragraph 50). The Office Action appears to overlook that there is not even an implicit suggestion that the ability of the pharmacist tool to prompt for refills could be adapted to initiate the appointment making tool to automatically

schedule an appointment without scheduling input contemporaneously provided by the patient for an appointment to replenish a drug in a device. Indeed, paragraph 12 of Mayer states that “health care maintenance methodologies to date fail to provide individuals with the degree of control and direct involvement over one’s own healthcare that can be provided from a patient-centric resource, and paragraph 13 of Mayer states: “The present invention comprises a set of software tools that can be used by a consumer (patient or individual) to take charge of his or her own medical or health care. Systems and methods of the present invention enable a patient(s) to store, maintain and track his/her own medical data.” See also the figures of Mayer, and paragraphs. 25, 30, 34, and 35 of Mayer which describe required patient input as shown in the figures of Mayer.

The visit report disclosed in paragraph 27 of Mayer requires input by a patient in order for the system to provide scheduling, prompting for and recordation of visit and follow-up visit reports. At best, automatic scheduling in Mayer is accomplished by scheduling input by the patient (paragraphs 50 and 27 of Mayer). Such scheduling is not the same as appointment scheduling automatically initiated by a drug scheduling module that has received data about the implantable drug delivery device comprising drug usage information and/or drug management data and has determined that the drug should be replenished. Accordingly, there would have been no reason for one of ordinary skill in the art to remove the patient from involvement with the appointment making tool as disclosed in paragraph 50 of Mayer and configure the pharmacist tool as disclosed in paragraph 39 of Mayer to initiate the separate appointment making tool sans patient involvement.

There is no suggestion to combine the teachings of the cited art as advanced in the Office Action to provide the invention as claimed in pending independent claim 12, except from using the applicant’s invention as a template through a hindsight reconstruction of applicant’s claims. Even if the proposed combination is proper, it does not result in the invention of pending claim 12 because there is a conceptual link missing between the disclosures of the two cited documents: a drug device with an audible alarm (Lebel) and an appointment making tool to be used by a patient that can automatically make an appointment (Mayer). Mayer teaches that its

tools allow patients to take control of their own health, and thus Mayer teaches away from the claimed invention, which does everything automatically.

Similar to Mayer, Lebel discloses a goal to “enhance user interface capabilities in ambulatory medical systems and in particular for implantable infusion pump systems.” Lebel thus also states a concern for greater user involvement and again it would not have made sense to eliminate user interaction by employing automatic appointment scheduling. Consequently, without the benefit of the disclosure of the present invention, it would not have been obvious to one of ordinary skill in the art to provide an appointment scheduling module automatically initiated by a drug scheduling module, as recited in the instant claims.

Independent claim 21 has also been amended to clarify the invention. Claim 21 has been amended to recite, in part:

a scheduling module coupled to the memory and the electronics, the scheduling module configured to calculate at least one relationship among the pump scheduling criteria and monitored pump variables, the scheduling module configured to decide automatically and without scheduling input contemporaneously provided by the patient whether an appointment is required, and the scheduling module configured to activate the telemetry module to schedule an appointment, wherein the scheduling module is adapted to contact via the telemetry module at least one entity for the appointment scheduling automatically, and without scheduling input contemporaneously provided by the patient, wherein the at least one entity is selected from the group consisting of a pharmacy, a caregiver, a physician, and a hospital.

The amendment is supported at least by paragraphs 52 and 58-59 and Figure 10 of the application as originally filed. Neither Lebel nor Mayer discloses the features of amended claim 21. As discussed above, Lebel teaches an external device that sounds an alarm to remind the patient to schedule an appointment, and does not disclose a scheduling module that decides automatically whether an appointment is required and initiates a telemetry module to schedule an appointment. As discussed above, at best, the system of Mayer only schedules an appointment at the request of a patient. There is no teaching or suggestion by Mayer that an appointment may be scheduled by a scheduling module of an implantable drug delivery device that is configured to calculate at least one relationship among the pump scheduling criteria and monitored pump variables, decide automatically whether an appointment is required, and which is configured to activate a telemetry module to schedule an appointment as claimed.

In sum, combining the features of Mayer with Lebel would not result in the embodiments recited in claims 12 or 21. Neither Lebel nor Mayer, alone or in combination, teach or suggest either an appointment scheduling module automatically initiated by a drug scheduling module or a scheduling module that automatically decides whether an appointment is required and initiates a telemetry module. Claims 13-15, 17-20 and 39-41 depend from claim 12 and claims 22-26 and 44-46 depend from claim 21, and are patentable over Lebel in view of Mayer for at least the same reasons as amended claims 12 and 21 and for the additional features recited therein.

Claim 16 was rejected under 35 USC §103(a) as being unpatentable over Lebel in view of Mayer, and further in view of Akers, et al., U.S. Patent No. 6,112,182 ("Akers"). Claim 16 depends from claim 12. Akers is directed to a data processing system for use in managing healthcare and does not remedy the deficiencies of Lebel and Mayer with respect to claim 12. Therefore claim 16 is patentable over Lebel in view of Mayer and further in view of Akers for at least the same reasons as amended claim 12, and for the additional features recited therein.

Claims 42-43 and 47-48 were rejected under 35 USC §103(a) as being unpatentable over Lebel in view of Mayer, and further in view of Cummings, Jr., et al., U.S. Patent No. 6,345,260 ("Cummings, Jr."). Claims 42-43 depend from claim 12 and claims 47-48 depend from claim 21. Cummings, Jr. is directed to an appointment scheduling interface for booking appointments with professionals. (See Col. 1, lines 13-16 of Cummings, Jr.) Cummings, Jr. does not remedy the deficiencies of Lebel and Mayer with respect to either claim 12 or claim 21. Cummings, Jr. does not teach or suggest at least an appointment scheduling module automatically initiated by a drug scheduling module or a scheduling module that initiates a telemetry module to schedule an appointment. Rather, Cummings, Jr., discloses a

"[C]all center, to which clients can call through conventional telephone lines. (Col. 6, lines 46-47) "While client 10b is on the line, call center 11 can log onto the Web from any Web browser. With proper security clearance and verification, server 15 permits access to online master schedule database 16, which contains and displays the appointment times and dates for all physicians on the system, i.e., showing those times when these physicians are willing to accept tentative appointment bookings." (Col. 8, lines 1-7)

Appointment scheduling is therefore disclosed by Cummings, Jr. to be initiated by a

*client call* to a call center.

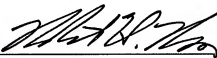
Accordingly, none of Lebel, Mayer nor Cummings, Jr., either alone or in combination, teach or suggest the inventions of independent claims 12 or 21. Claims 42-43 depend from claim 12 and claims 47-48 depend from claim 21, and are patentable over Lebel in view of Mayer and Cummings, Jr. for at least the same reasons as amended claims 12 and 21 and for the additional features recited therein. Reconsideration and withdrawal of the 35 USC §103(a) rejections are respectfully requested.

**CONCLUSION**

Applicants therefore respectfully request reconsideration of the pending claims and a finding of their allowability. A notice to this effect is respectfully requested. The Examiner is welcome to contact via telephone the undersigned should it be helpful to facilitate prosecution of the application.

Respectfully submitted,

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By:   
Robert H. Resis  
Registration No. 32,168  
Direct Dial: (312) 463-5405